REMARKS

This Paper, Request for Continued Examination, and Petition for a one-month extension of time are submitted in response to the Advisory Action dated January 15, 2006 and the final Office Action mailed on October 18, 2005 having a shortened statutory response period that ended on January 18, 2006. This Paper is timely submitted within one month of the shortened statutory response period namely, February 18, 2006. The Commissioner is hereby authorized to charge any additional fees to Deposit Account number 02-1818.

Claims 76-78, 80-94, and 105-108 are pending in this application. Support for claim 76 may be found at page 9 lines 8-14, page 10 lines 1-6, page 11 lines 9-14 (*e.g.*, the syringe bodies "remain unwrapped....") of the present specification. In view of the present specification and the aforementioned sections thereof in particular, one of ordinary skill in the art would recognize that the syringe bodies are unwrapped during at least the transferring step.

Claims 105, 106, and 108 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by U.S. Patent No. 6,800,245 to Erbe et al. (*Erbe*). Claim 107 was rejected under 35 U.S.C. §103(a) for allegedly being obvious in view of *Erbe*. Claims 76-78, 80-87, 90, and 91 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over *Erbe* in view of U.S. Patent No. 5,620,425 to Heffernan et al. (*Heffernan*) and U.S. Patent No. 3,780,308 to Nablo (*Nablo*). Claims 88-89 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Erbe*, in view of *Heffernan*, *Nablo*, and in further view of U.S. Patent No. 6,164,044 to Porfano et al. (*Porfano*). Claims 92-94 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Erbe* in view of *Heffernan* and *Nablo* and in further view of U.S. Patent No. 5,207,983 to Liebert et al. (*Liebert*). Applicants respectfully disagree with and traverse these alleged rejections as no combination of *Erbe*, *Heffernan*, *Nablo*, *Porfano*, and *Liebert* teaches or suggests the subject matter recited in the present claims.

Erbe has no disclosure directed to 1) the formation of cyclic olefin copolymer containing syringe bodies or 2) the transfer of sterile unwrapped syringe bodies on a transfer mechanism into a sterile enclosed isolator class 100 environment as recited in independent claim 76. *Erbe* discloses a method for preparing a kit that includes filling paste into cartridges. The filling process occurs in an isolator. *Erbe*, col. 12 line 42 through col. 13 line 11. The cartridges may be sterilized prior to the filling process. *Erbe*, col. 11 lines 40-63, col. 12 lines 19-27. *Erbe*, however, has no disclosure whatsoever regarding the composition of the cartridges. Moreover,

Erbe has no disclosure directed to how the cartridges are placed into the sterile environment. As *Erbe* is silent regarding the composition of the cartridges and how the cartridges are placed in the isolator, *Erbe* fails to disclose or suggest a method of producing sterile prefilled syringe bodies of cyclic olefin copolymer and the transfer of sterile unwrapped syringe bodies into an enclosed isolator class 100 environment as recited in claim 76.

Heffernan has no disclosure whatsoever regarding 1) the formation of cyclic olefin copolymer containing syringe bodies or 2) the transfer of syringe bodies along a transfer mechanism. Rather, *Heffernan* discloses the formation of polypropylene syringe bodies. *Heffernan*, col. 5 lines 60-62. In addition, *Heffernan* is wholly silent regarding the transfer of unwrapped sterilized syringe bodies into a class 100 environment. Indeed, *Heffernan* suggests that sterilized syringe barrels are wrapped in heat-sealed bags and subsequently delivered to a clean room for filling and assembly. *Heffernan*, col. 6 lines 12-20. As *Heffernan* has no disclosure directed to the formation of cyclic olefin copolymer containing syringe bodies and the transfer of sterile unwrapped syringe bodies into a isolator class 100 environment, *Heffernan* does not disclose or suggest the subject matter of independent claim 76.

Nablo fails to teach or suggest a method of producing filled sterile syringes that includes 1) forming cyclic olefin copolymer containing syringe bodies and transferring sterilized syringe bodies into 2) a sterile enclosed isolator class 100 environment as recited in independent claim 76. *Nablo* has no disclosure whatsoever directed to the formation of syringe bodies let alone injection molded cyclic olefin copolymer containing syringe bodies. Moreover, *Nablo* does not disclose a sterile enclosed isolator class 100 environment. Rather, *Nablo* discloses the surface sterilization of packaging material with electron beam radiation. *Nablo*, col. 1 lines 3-8. Ozone, inert gas, secondary x-rays, or a surface sterilizer may be used to maintain a sterile condition during filling and sealing of containers. *Nablo*, col. 5 line 58 through col. 6 line 18. *Nablo*, however, has no disclosure whatsoever directed to an enclosed isolator class 100 environment. Indeed, *Nablo* suggests an open system as Figures 4, 5a, and 5b illustrate an open production process. As *Nablo* has no disclosure directed to 1) forming cyclic olefin copolymer containing syringe bodies, 2) an enclosed class 100 environment, and 3) suggests an open system, *Nablo*, alone or in combination, fails to disclose or suggest the subject matter of independent claim 76.

Porfano teaches away from a method of producing sterile prefilled syringe bodies that includes transferring a plurality of unwrapped sterilized syringe bodies into a sterile environment

as recited in independent claim 76. *Porfano* discloses syringe barrels placed in a tub in a sealed plastic bag. *Porfano*, col. 7 lines 22-37. The packaged and wrapped syringe bodies are subsequently shipped to a clean room for filling and assembly. *Porfano*, col. 7 line 38 through col. 8 line 17; FIG. 9 and 11. As *Porfano* discloses syringe bodies that are sealed in a plastic bag and transferred to a clean room, *Porfano* teaches away from transferring unwrapped sterile syringe bodies into a sterile environment as recited in independent claim 76.

Liebert fails to fulfill the deficiencies of *Erbe*, *Heffernan*, and/or *Nablo* as *Liebert* has no disclosure directed to 1) the formation of cyclic olefin copolymer containing syringe bodies and 2) the sterilization of syringe bodies with electron beam radiation. *Liebert* merely discloses terminal sterilization of filled syringes by autoclaving. *Liebert*, col. 2 lines 8-9.

Erbe, *Heffernan*, *Nablo*, and *Liebert*, either alone or in combination, fail to disclose or suggest the formation of cyclic olefin copolymer containing syringe bodies. *Erbe*, *Heffernan*, and *Liebert* fail to disclose or suggest the transfer of sterile unwrapped syringe bodies into an enclosed isolator class 100 environment. *Porfano* teaches away from the transfer of sterile unwrapped syringe bodies into an enclosed isolator. In view of the foregoing, independent claim 76 and the claims depending therefrom are novel and nonobvious over the cited references.

Regarding independent claim 105 and the claims depending therefrom, it is a well settled axiom of patent law the every word in a claim must be considered in judging patentability of the claim. *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995); *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Thus, when claim 105 is properly interpreted, it is clear that *Erbe* fails to disclose or suggest a method of producing sterile prefilled syringe bodies that includes irradiating a syringe body with electron beam radiation during the transfer of the syringe body to a sterile environment. *Erbe* discloses that cartridges may be sterilized via electron beam radiation. *Erbe*, col. 8 lines 18-20. *Erbe*, however, has no disclosure whatsoever regarding the sterilization of cartridges during the transfer thereof into a sterile environment. Rather, *Erbe* discloses that the packaging (*e.g.*, the cartridges) are sterilized in Step 30. The cartridges are subsequently introduced into an isolator where the cartridges are filled with paste and assembled in Step 70. *Erbe*, col. 12 line 19 through col. 13 line 11, FIG. 1. *Erbe* has no disclosure directed to how the cartridges arrive in the isolator. Indeed, *Erbe* is wholly silent regarding a transfer step, let alone a transfer step that includes sterilizing the

cartridges during the transfer step. As *Erbe* is wholly silent regarding this recited claim element, *Erbe* does not teach or suggest the subject mater of claims 105-108.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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